

**Centers for Disease Control and Prevention
Model Performance Evaluation Program
Human Immunodeficiency Virus Type 1 (HIV-1)
Testing for p24 Antigen**

**Figures Used for the Analysis
of the June 29, 1998 Performance Evaluation
Testing Results Reported by Participant Laboratories**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Report of the June 29, 1998 Human Immunodeficiency Virus Type I (HIV-1) p24 Antigen Performance Evaluation Sample Testing Results Provided by Participant Laboratories in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC).

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**SUPPLEMENTAL INFORMATION FOR COMPREHENDING
THE NUMBERS USED TO LABEL FIGURES
IN THIS REPORT**

The "N=" that appears on each graph represents the number of laboratories that reported results. For some graphs, laboratories reported results using more than one test kit for a specific test type; therefore, the AN= may exceed the actual number of laboratories participating in the survey. In figures 1-3 and 5-6, the vertical axis is labeled either as frequency of results or percentage of reporting laboratories; in figure 4, the horizontal axis is labeled as percentage of reporting laboratories. In all figures, the number appearing directly above each bar represents a frequency of results only.

Centers for Disease Control and Prevention (CDC)
Model Performance Evaluation Program for
Human Immunodeficiency Virus Type I (HIV-1) p24 Antigen Testing

Table 1. CDC HIV-1 p24 Antigen Testing Results for the June 29, 1998 Participant Laboratory Panel Samples

| Panel Letter Interpretation ² | Vial Label | CDC Donor Number | CDC Test Results ¹ | Test Kit Manufacturer | CDC |
|--|------------|------------------|---|---|----------------------------------|
| A | A1, A4 | 01 | p24 Antigen detected p24 Antigen detected p24 Antigen detected | Abbott HIVAG-1 MAb ³ Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Positive Positive Positive |
| | A2 | 03 | No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Negative Negative Negative |
| | A3 | 02 | p24 Antigen detected p24 Antigen detected p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Positive Positive Positive |
| | A5 | 04 | No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Negative Negative Negative |
| B | B1 | 04 | No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Negative Negative Negative |
| | B2, B5 | 01 | p24 Antigen detected p24 Antigen detected p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Positive Positive Positive |
| | B3 | 03 | No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Negative Negative Negative |
| | B4 | 02 | p24 Antigen detected p24 Antigen detected p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Positive Positive Positive |
| C | C1, C3 | 01 | p24 Antigen detected p24 Antigen detected p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Positive Positive Positive |
| | C2 | 04 | No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Negative Negative Negative |
| | C4 | 03 | No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Negative Negative Negative |
| | C5 | 02 | p24 Antigen detected p24 Antigen detected p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Positive Positive Positive |
| D | D1 | 02 | p24 Antigen detected p24 Antigen detected p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Positive Positive Positive |
| | D2, D4 | 01 | p24 Antigen detected p24 Antigen detected p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Positive Positive Positive |
| | D3 | 04 | No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Negative Negative Negative |
| | D5 | 03 | No p24 Antigen detected No p24 Antigen detected No p24 Antigen detected | Abbott HIVAG-1 MAb Coulter HIV-1 p24 Antigen Organon HIV-1 Antigen | Negative Negative Negative |

¹ Result based on testing performed in two separate laboratories.

² The CDC interpretation is consistent with the manufacturer's criteria for interpretation of results.
Positive = Presence of HIV-1 p24 antigen confirmed; Negative = p24 antigen not detected

³ **MAb = monoclonal antibody**

Figure 1. Frequency of HIV-1 p24 Antigen Test Result Interpretations, by Sample Type (Reactivity), for Qualitative and Neutralization Tests Reported by Participant Laboratories for the June 29, 1998 Shipment

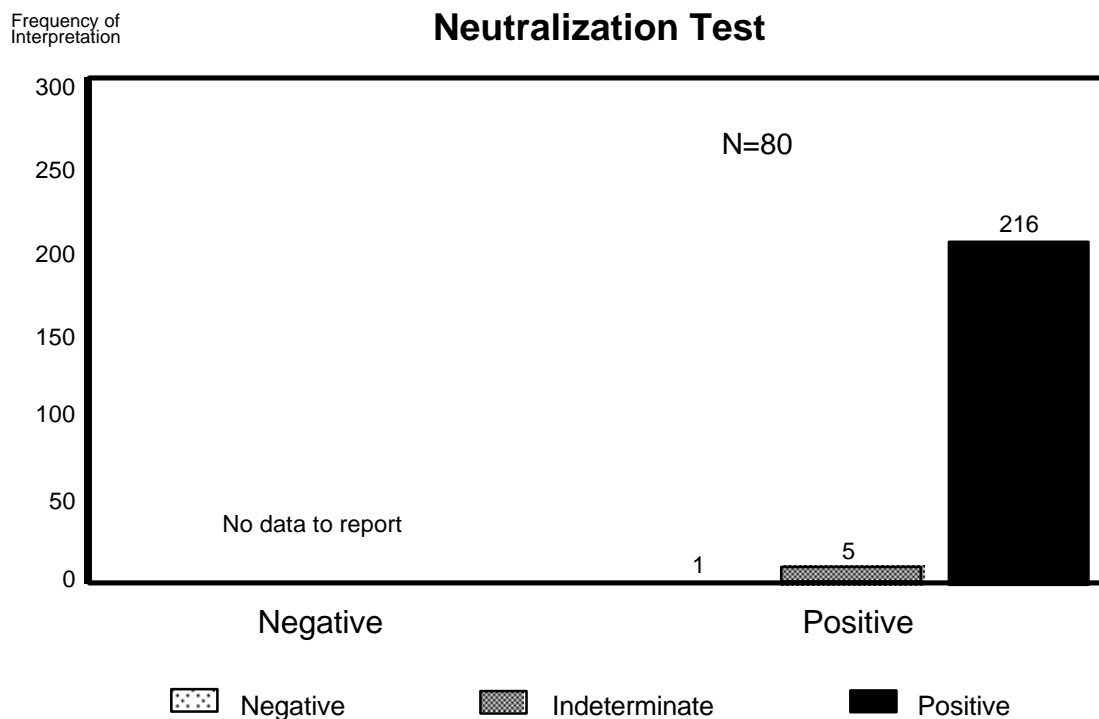
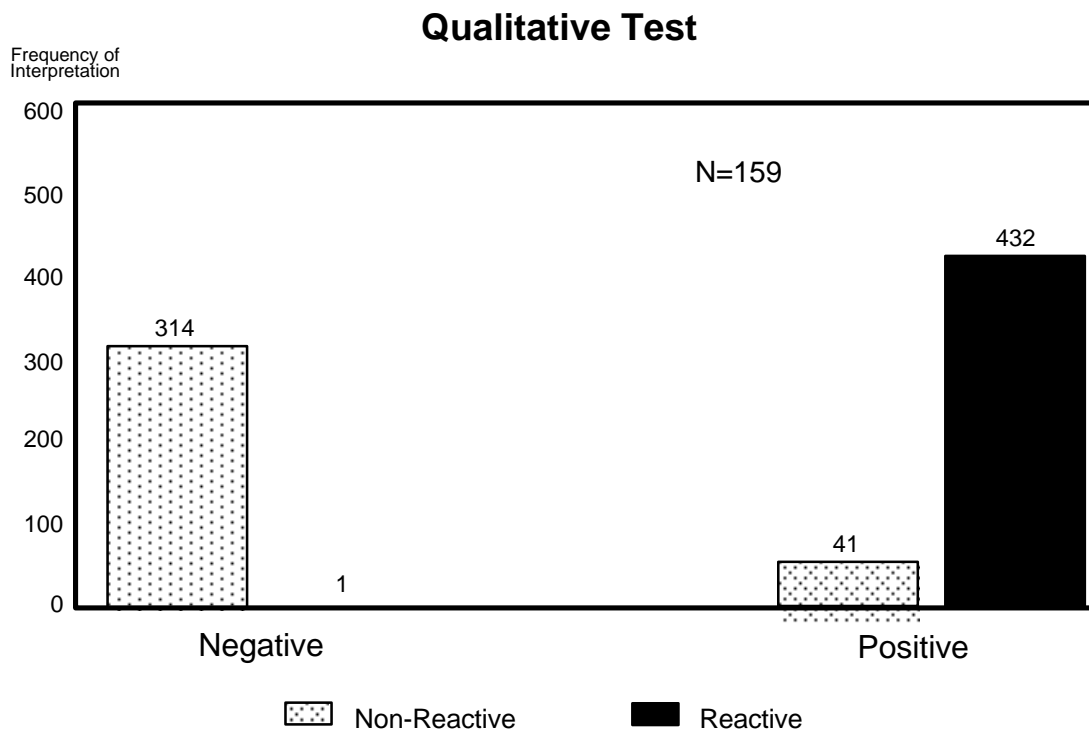


Figure 2. Percentage of Participant Laboratories, by Laboratory Type, that Reported HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Results to the CDC for the June 29, 1998 Shipment

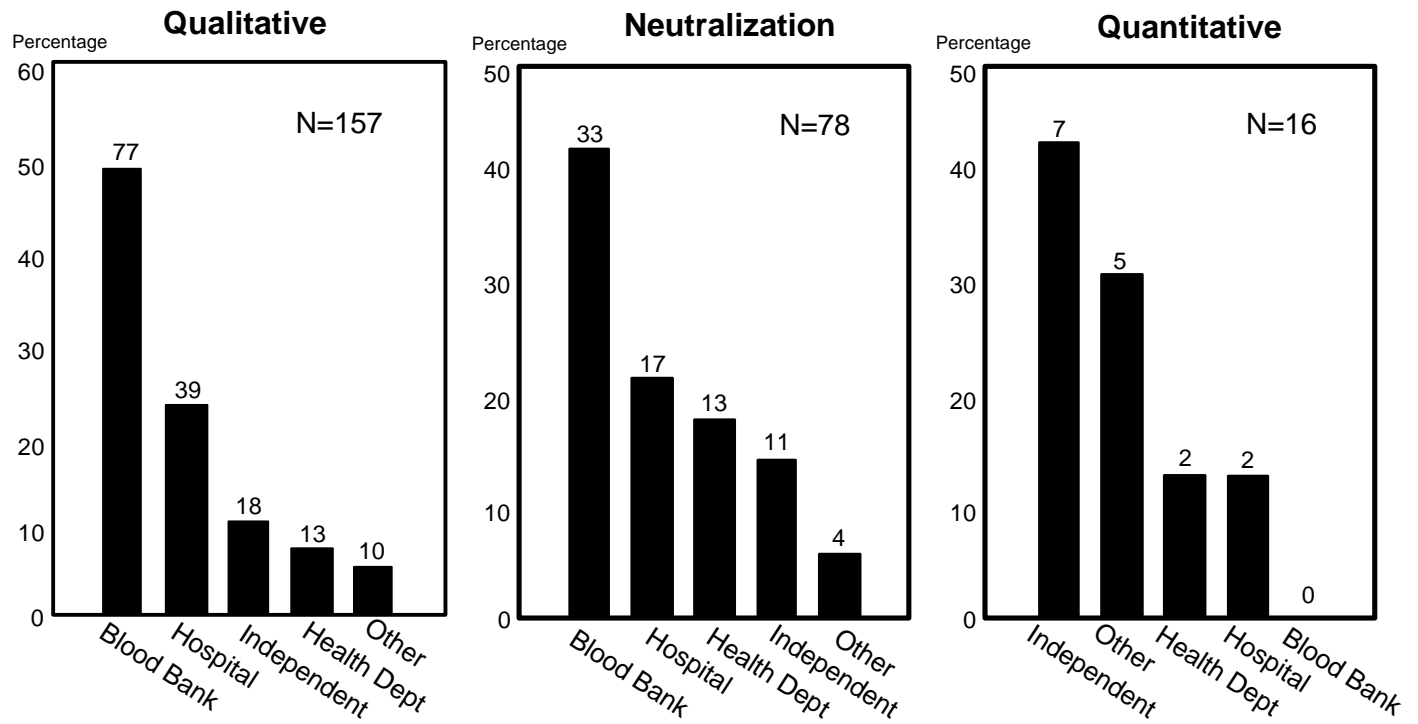


Figure 3. Combination of HIV-1 p24 Antigen Tests Reported by Participant Laboratories for the June 29, 1998 Shipment

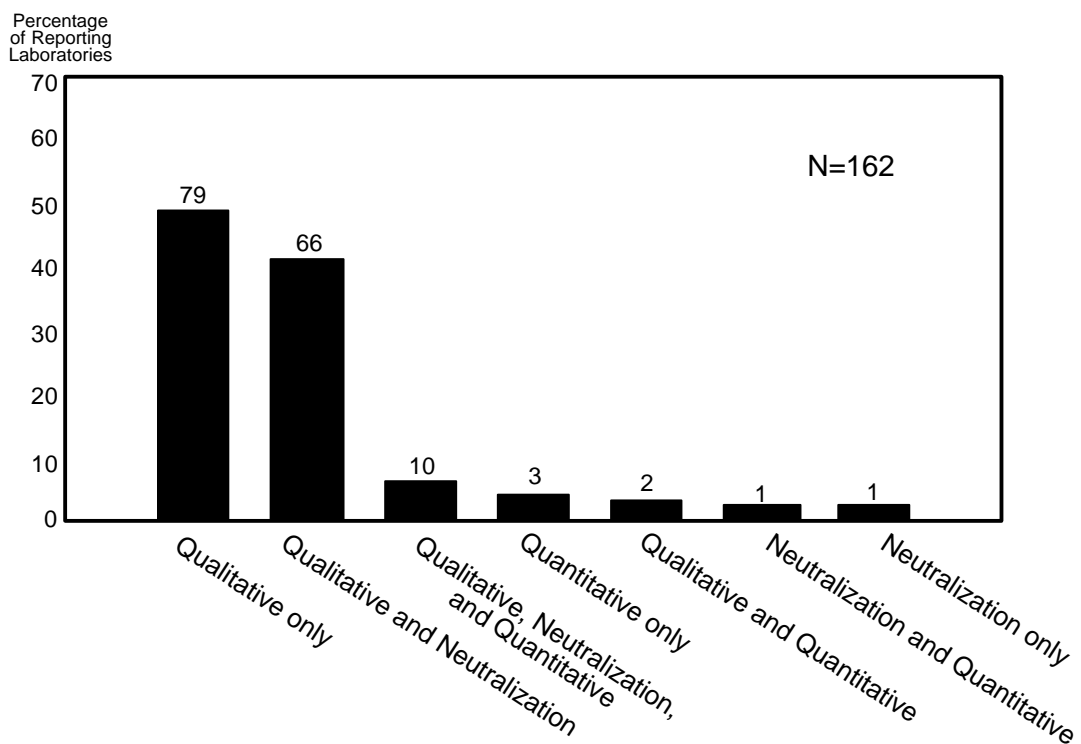
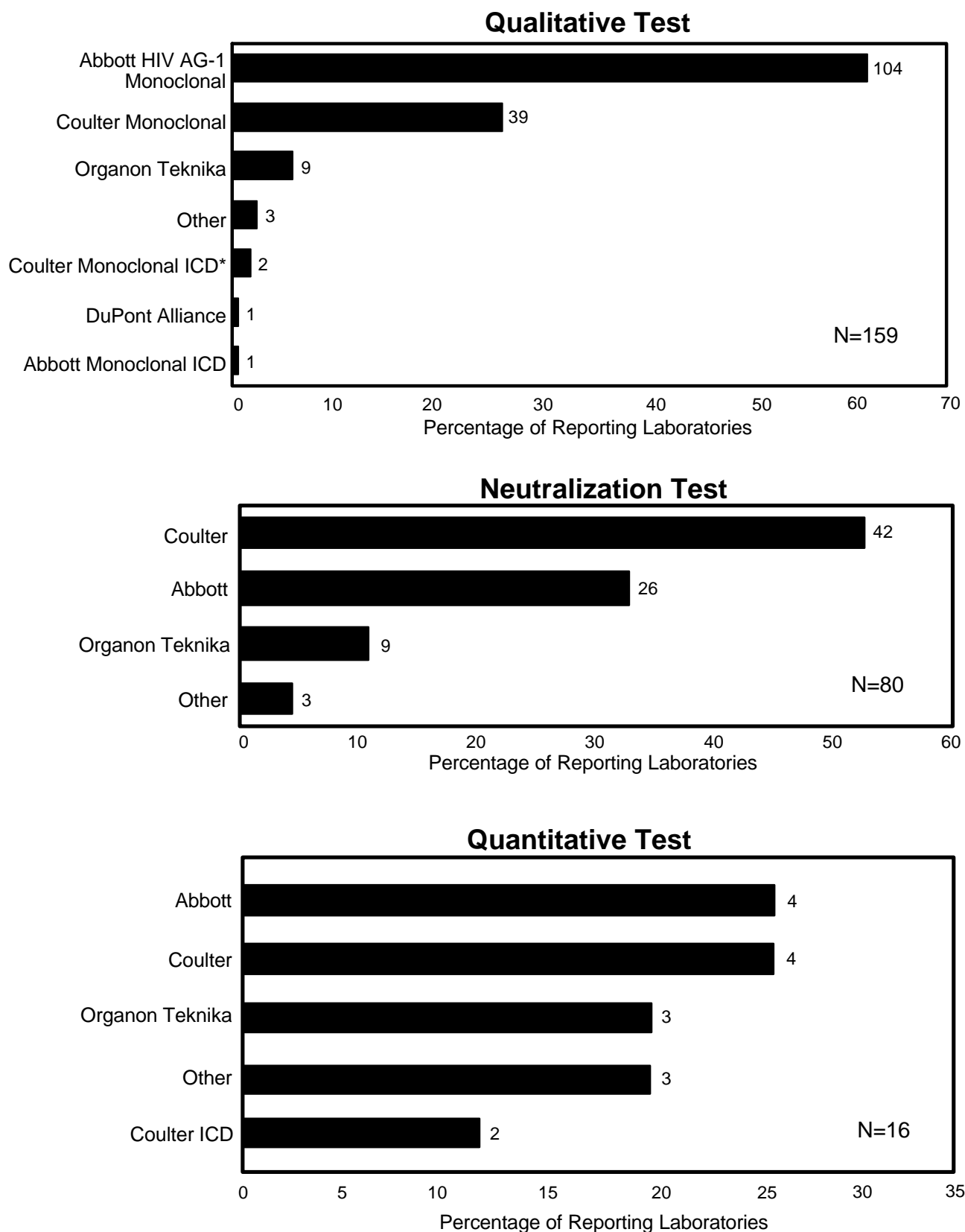


Figure 4. Types of Test Kits Used for HIV-1 p24 Antigen Qualitative, Neutralization, and Quantitative Tests Reported to CDC by Participant Laboratories in the June 29, 1998 Shipment



*ICD=Immune Complex Dissociation

Figure 5. HIV-1 p24 Antigen Qualitative Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the June 29, 1998 Shipment

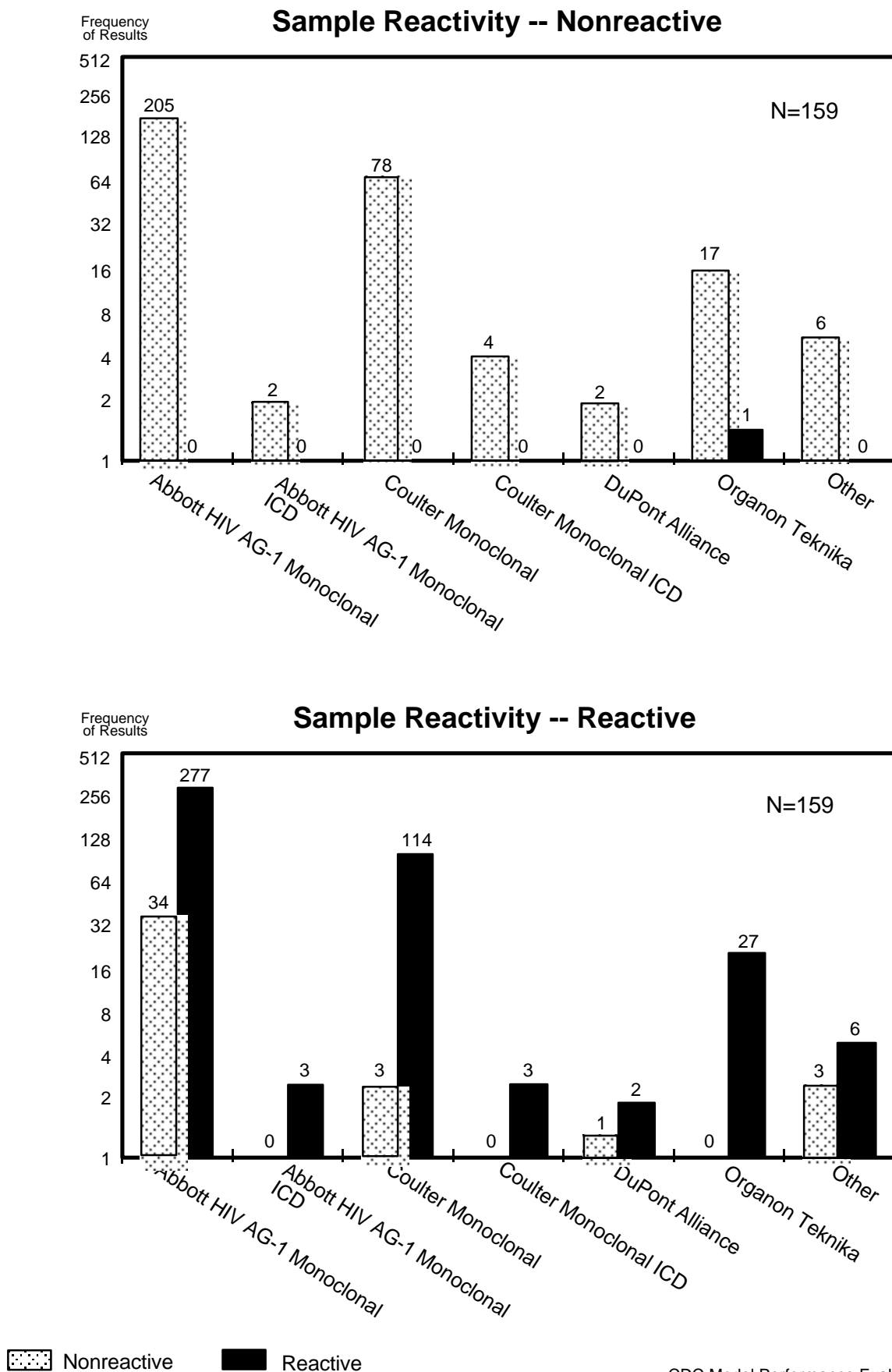


Figure 6. HIV-1 p24 Antigen Neutralization Test Results, by Kit Manufacturer, Reported by Participant Laboratories for the June 29, 1998 Shipment

Sample Reactivity -- Negative

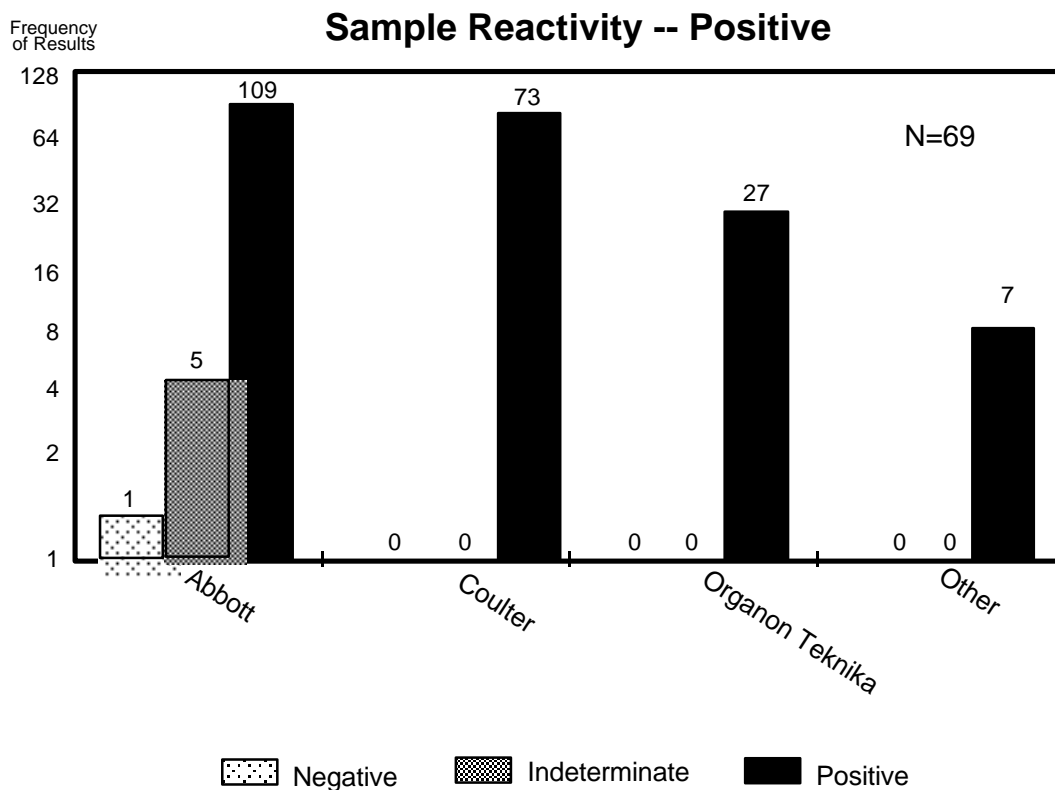
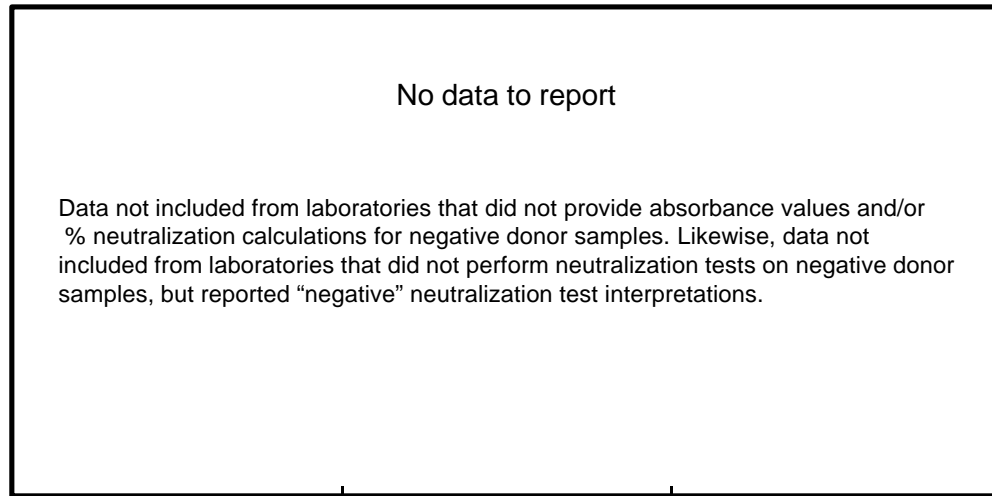


Table 2. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the June 29, 1998 Performance Evaluation Shipment

CDC Donor #1
Donor Status: HIV-1 Infected
Panel Vial Labels: A1, B2, C1, D2

| Test Kit | No. of Results Confirming p24 | No. of Results Not Confirming p24 | Range of Results Reported % Neutralization | | |
|-----------------|-------------------------------|-----------------------------------|--|--------|---------|
| | | | minimum | median | maximum |
| Abbott | 42 | 0 | 71.0 | 89.1 | 120.8 |
| Coulter | 25 | 0 | 61.9 | 79.8 | 99.5 |
| Organon Teknika | 9 | 0 | 79.5 | 87.0 | 91.9 |
| Other | 3 | 0 | 98.8 | 99.0 | 100.0 |

CDC Donor #1 - Duplicate
Donor Status: HIV-1 Infected
Panel Vial Labels: A4, B5, C3, D4

| Test Kit | No. of Results Confirming p24 | No. of Results Not Confirming p24 | Range of Results Reported % Neutralization | | |
|-----------------|-------------------------------|-----------------------------------|--|--------|---------|
| | | | minimum | median | maximum |
| Abbott | 42 | 0 | 63.5 | 89.5 | 121.2 |
| Coulter | 25 | 0 | 58.2 | 75.9 | 101.0 |
| Organon Teknika | 9 | 0 | 83.2 | 89.0 | 93.6 |
| Other | 3 | 0 | 98.8 | 100.4 | 103.4 |

Table 2. Results of the HIV-1 p24 Antigen Neutralization Test Reported by Participant Laboratories for the June 29, 1998 Performance Evaluation Shipment (Continued)

CDC Donor #2
Donor Status: HIV-1 Infected
Panel Vial Labels: A3, B4, C5, D1

| Test Kit | No. of Results Confirming p24 | No. of Results Not Confirming p24 | Range of Results Reported % Neutralization | | |
|-----------------|-------------------------------|-----------------------------------|--|--------|---------|
| | | | minimum | median | maximum |
| Abbott | 25 | 6 | 47.7 | 68.3 | 114.3 |
| Coulter | 23 | 0 | 51.2 | 76.5 | 97.9 |
| Organon Teknika | 9 | 0 | 82.3 | 89.5 | 92.0 |
| Other | 1 | 0 | 97.6 | 97.6 | 97.6 |

Table 3. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the June 29, 1998 Performance Evaluation Shipment

CDC Donor #1

Donor Status: HIV-1 Infected

Panel Vial Labels: A1, B2, C1, D2

| Test Kit | No. of Results Quantitating p24 | No. of Results Not Quantitating p24 | Range of Results Reported Concentration (pg/ml) | | |
|-----------------|---------------------------------|-------------------------------------|---|--------|---------|
| | | | minimum | median | maximum |
| Abbott | 4 | 0 | 9.5 | 34.7 | 97.4 |
| Abbott ICD | 1 | 0 | 86.0 | 86.0 | 86.0 |
| Coulter | 2 | 0 | 19.4 | 24.2 | 29.0 |
| Coulter ICD | 4 | 0 | 44.0 | 201.0 | 268.5 |
| Organon Teknika | 3 | 0 | 16.2 | 20.2 | 64.9 |
| Other | 3 | 0 | 7.5 | 115.7 | 120.0 |

CDC Donor #1 - Duplicate

Donor Status: HIV-1 Infected

Panel Vial Labels: A4, B5, C3, D4

| Test Kit | No. of Results Quantitating p24 | No. of Results Not Quantitating p24 | Range of Results Reported Concentration (pg/ml) | | |
|-----------------|---------------------------------|-------------------------------------|---|--------|---------|
| | | | minimum | median | maximum |
| Abbott | 4 | 0 | 8.6 | 30.6 | 63.1 |
| Abbott ICD | 1 | 0 | 99.5 | 99.5 | 99.5 |
| Coulter | 2 | 0 | 18.8 | 20.9 | 23.0 |
| Coulter ICD | 4 | 0 | 39.0 | 204.5 | 252.7 |
| Organon Teknika | 3 | 0 | 16.3 | 16.4 | 66.0 |
| Other | 3 | 0 | 9.2 | 110.0 | 130.0 |

Table 3. Results of the HIV-1 p24 Antigen Quantitative Test Reported by Participant Laboratories for the June 29, 1998 Performance Evaluation Shipment (Continued)

CDC Donor #2
Donor Status: HIV-1 Infected
Panel Vial Labels: A3, B4, C5, D1

| Test Kit | No. of Results Quantitating p24 | No. of Results Not Quantitating p24 | Range of Results Reported Concentration (pg/ml) | | |
|-----------------|---------------------------------|-------------------------------------|---|--------|---------|
| | | | minimum | median | maximum |
| Abbott | 2 | 0 | 100.0 | 110.5 | 121.0 |
| Abbott ICD | 1 | 0 | 189.3 | 189.3 | 189.3 |
| Coulter | 2 | 0 | 9.1 | 15.1 | 21.0 |
| Coulter ICD | 3 | 0 | 24.0 | 673.5 | 785.0 |
| Organon Teknika | 3 | 0 | 13.3 | 21.3 | 66.4 |
| Other | 3 | 0 | 3.5 | 144.8 | 182.0 |